

REMARKS

The Office Action mailed March 6, 2006 has been carefully considered and the following is responsive thereto. Claims 1-45 are pending in the present application. Claims 24-26 have been amended to delete the second occurrence of "of" in the first line. Claim 43 has been amended to state that the reduced molecular weight carrageenan is used in an amount of at least 70% of all carrageenan present in the composition. Claim 43 has been amended to state that the gel film has a solids content of at least 40% and the low molecular weight carrageenan is present in an amount of at least 70% of all carrageenan present in the gel film. Support for the amendments to claims 43 and 44 can be found throughout the specification and in claim 1. No new matter has been added.

At page 2 of the Office Action, the Examiner rejected claim 43 under 35 USC 112, second paragraph as being indefinite because the term "solution" in the last line lacks a clear antecedent basis.

Applicants traverse this rejection. The term "solution" has a clear antecedent basis in line 5 of claim 43 which recites "0.10 molar aqueous sodium chloride solution." Withdrawal of this section 112, second paragraph rejection is requested.

At page 2 of the Office Action, the Examiner provisionally rejected claims 44 and 45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 20, 21 and 23-27 of copending application Serial No. 10/824,793.

Applicants request that this rejection be held until such time as notice of patentable subject matter has been received in the applications. Applicants will file an appropriate terminal disclaimer at that time if necessary.

At page 4 of the Office Action, the Examiner rejected claims 1, 6, 7 and 28 under 35 USC 103 as being obvious over Guiseley (U.S. Patent 4,443,486). The basis for this rejection is that it would be obvious to substitute the carrageenan extract of *Eucheuma cottonii* seaweed disclosed in Guiseley for the carrageenan containing Irish moss seaweed in gel puddings such as blanc mange to improve the taste and texture of the pudding.

Applicants traverse this rejection. Claims 1, 6 and 7 are directed to homogeneous, thermoreversible gels comprising carrageenan wherein the carrageenan has a viscosity of 5 to less than 10 cP at 75 °C when measured in a 0.10 molar aqueous sodium chloride solution

containing 1.5% by weight of the carrageenan based on the weight of all components in the solution, and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent, wherein the gel has a solids content of at least 40% and the carrageenan is present in an amount of at least 70% of all carrageenan present in the gel. Claim 28 is directed to an edible product comprising the gel of claims 1-26.

Guiseley mentions that, as background, carrageenan generally had been used to prepare milk puddings such as blanc mange (column 1, lines 40-46). The invention in Guiseley relates to the use of a particular low molecular weight carrageenan extract to stabilize chocolate milk. More particularly, the invention in Guiseley is directed to a stabilizer for milk products comprised of a carrageenan extract of *Eucheuma cottonii* seaweed having a water viscosity of at 1.5% concentration and 75°C of not less than 5 m.Pa.s and not more than about 20 m.Pa.s.¹ Importantly, the low molecular weight carrageenan extract of Guiseley is disclosed to be desirable as a stabilizer for chocolate milk because it is indicated therein that it will not undesirably lead to gelation. For example, as disclosed in column 5, lines 29-42, Guiseley discusses the advantages of the low molecular weight carrageenan extract for stabilizing chocolate milk:

One such performance advantage of the modified *Eucheuma cottonii* extractive of this invention is its ability to provide stabilization of chocolate milk at relatively high use levels without excessive thickening of the product, such as results when conventional carrageenan stabilizers are employed. This characteristic of the modified extractive of this invention is of particular importance in those circumstances where the chocolate milk is subjected to extreme shear stresses during processing, and the dairyman wishes to provide stabilization *without running the risk of gelation*, as is encountered when using a more conventional stabilizer at a high enough level to accommodate for the effects of shear stresses. (Emphasis added.)

It is clear that Guiseley does not disclose the gels of the present invention. Moreover, Guiseley does not suggest the gels of the present invention because, as noted above, it actually teaches away from the gels of the present invention as it discloses that the low molecular weight

¹ Applicants note that the viscosity of the low molecular weight materials disclosed in Guiseley is measured in a 1.5% water solution, whereas the viscosity of the low molecular weight materials of the present invention is measured in a 1.5% sodium chloride solution.

materials disclosed therein are desirable for use as a stabilizer for chocolate milk because such materials may be used "*without running the risk of gelation*" (emphasis added).

In addition, the reference does not disclose or suggest the gels of the present invention wherein the gel has a solids content of at least 40% and the low molecular weight carrageenan of the invention is present in an amount of at least 70% of all carrageenan present in the gel.

As discussed in the present specification at page 2, in high solids systems, for example, greater than 40% solids, carrageenan gel forming compositions have generally been known to create highly viscous systems that create processing problems when the gel is made. Processing requires significant heat, shear and handling in order to prevent premature gelling or formation of gels and gel films that are less than fully homogeneous (resulting in gels of weaker strength). Important industrial applications, such as the manufacture of soft capsules, hard capsules, edible products (gummies, candies, etc.), solid forms encapsulating powders, tablets, etc., could benefit from the use of particular carrageenan gels that gel at reduced temperatures. It has long been believed that the gelling temperature of carrageenan is independent of its molecular weight. To Applicants' surprise, in high solids carrageenan gels, such as at least 40% solids, the gels and gel films containing reduced molecular weight carrageenans as disclosed in the present application result in a highly desirable lowering of the gelling temperature. The gelling temperature is significantly reduced in such gels as shown at pages 7 and 8 of the specification. Lower gelling temperatures of the gels considerably benefits processing of the gels and overcomes problems associated with high gelling temperatures. Nothing in Guiseley suggests the lowering of the gelling temperatures in a high solids system when using the low molecular weight carrageenan of the present invention.

In view of the foregoing, it is respectfully submitted that the gels of claims 1, 6 and 7 and the edible product of claim 28 are not obvious in view of Guiseley. Accordingly, withdrawal of this section 103 rejection is requested.

At page 5 of the Office Action the Examiner rejected claims 2-5, 8-27, 29, 30-34, 44 and 45 under 35 USC 103 as being unpatentable over Guiseley (U.S. Patent No. 4,443,486) as applied to claims 1, 6, 7 and 28 above, and further in view of Gennadios (U.S. Patent No. 6,214,376). The Examiner's position is that it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the carrageenan extract of Guiseley for the carrageenan in Gennadios in view of the recognition in the art, as purportedly evidenced by

the Gennadios patent, that carrageenan is an effective ingredient for gel-forming products which can be consumed orally in various forms from capsule filled materials to edible dessert gels.

Applicants traverse this rejection. Claims 2-5, 8-27, 29, 30-34, 44 and 45 are directed to homogeneous, thermoreversible gels or capsules, solid forms or delivery systems containing such gels, wherein the gels contain carrageenan that has a viscosity of 5 to less than 10 cP at 75 °C when measured in a 0.10 molar aqueous sodium chloride solution containing 1.5% by weight of the carrageenan based on the weight of all components in the solution, wherein the gel has a solids content of at least 40% and said carrageenan is present in an amount of at least 70% of all carrageenan present in said gel.

Applicants respectfully traverse this rejection for the same reasons set forth above in regard to Guiseley. That is, Guiseley does not disclose or suggest the gels of the present invention because, as noted above, it does not disclose the gels of the present invention comprising the claimed low molecular weight carrageenan and it actually teaches away from the gels of the present invention as it discloses that the low molecular weight materials disclosed therein are desirable for use as a stabilizer for chocolate milk because such materials may be used "*without running the risk of gelation*" (emphasis added). Moreover, the Guiseley reference does not disclose or suggest the gels of the present invention wherein the gel has a solids content of at least 40% and the low molecular weight carrageenan of the invention is present in an amount of at least 70% of all carrageenan present in the gel nor suggest the beneficial lowering of the gelling temperatures associated with the use of such materials.

Gennadios does not cure the deficiencies of Guiseley. Gennadios discloses compositions useful for preparing gelatin-free capsules for oral administration of medicines, cosmetic or bath applications, or dietary supplements and methods for preparing the compositions. The compositions are disclosed to contain 0.5 to 12% by weight of kappa carrageenan, where the kappa carrageenan comprises at least 50% by weight of all film-forming material in the composition. Part of the kappa carrageenan can be substituted by iota carrageenan (up to a maximum of 50% or 25% by weight of the kappa carrageenan), which, according to the patent, forms "softer" and more elastic gels.

After reading Guiseley, nothing in Gennadios discloses or suggests that gels may in fact be formed by a carrageenan that has a viscosity of 5 to less than 10 cP at 75 °C when measured in a 0.10 molar aqueous sodium chloride solution containing 1.5% by weight of the carrageenan

based on the weight of all components in the solution. Nor does Gennadios suggest that gels having a solids content of at least 40% may be formed from the low molecular weight carrageenan of the invention being present in an amount of at least 70% of all carrageenan present in the gel nor suggest the beneficial lowering of the gelling temperatures associated with the use of such materials. One reading both references would conclude that the low molecular weight materials of Guiseley ought not to be used in Gennadios as such materials avoid the risk of gelation.

In view of the foregoing, it is submitted that claims 2-5, 8-27, 29, 30-34, 44 and 45 are not obvious over Guiseley in view of Gennadios. Withdrawal of this section 103 rejection is requested.

At page 8 of the Office Action, the Examiner rejected claims 35-43 under 35 USC 103 as being unpatentable over Gennadios (U.S. Patent 6,214,376) in view of Guiseley (U.S. Patent 4,443,486). The Examiner's position is that it would have been obvious to one of ordinary skill in the art to further subject the carrageenan used in the preparation of gels and capsules of the Gennadios patent to hydrolysis in order to reduce the viscosity of carrageenan thereof in view of the recognition in the art, as purportedly evidenced by the Guiseley patent, that carrageenan having such viscosity is an effective ingredient for gel-forming products which can be consumed orally in various forms from capsule filled materials to edible dessert gels.

Applicants traverse this rejection for the reasons set forth above. Claims 35-43 are directed to processes for making the gels claimed in the present application, processes for making soft capsules and a method for lowering the gelling temperature of a composition having at least 40% solids and containing the low molecular weight carrageenan of the invention in an amount of at least 70% of all carrageenan present in the gel.

Gennadios and Guiseley are discussed above. One reading Gennadios, which is directed to films, soft capsules, etc. comprising kappa carrageenan as a film former, would not have been motivated to use the low molecular weight materials disclosed in Guiseley since Guiseley teaches that the low molecular weight materials disclosed therein for chocolate milk stabilization are beneficial because they may be used "*without running the risk of gelation*" (emphasis added).

There is nothing about the references, in any order or combination, that discloses or suggests processes for making gels comprising a carrageenan that has a viscosity of 5 to less than 10 cP at 75 °C when measured in a 0.10 molar aqueous sodium chloride solution containing

1.5% by weight of the carrageenan based on the weight of all components in the solution. Nor is there anything in the references, in any order or combination, that suggests processes for making gels having a solids content of at least 40% from the low molecular weight carrageenan of the invention when present in an amount of at least 70% of all carrageenan present in the gel nor that suggests the beneficial lowering of the gelling temperatures associated with the use of such materials. One reading both references would conclude that the low molecular weight materials of Guiseley ought not to be used in Gennadios as such materials are taught to avoid the risk of gelation.


In view of the above, it is submitted that the methods of claims 35-43 are not obvious over Gennadios in view of Guiseley. Withdrawal of this section 103 rejection is requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 10884-00018-US. A duplicate copy of this paper is enclosed.

Dated: *August 7, 2006*

Respectfully submitted,

By 
Liza D. Hohenschutz
Registration No.: 33,712
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, Delaware 19899
(302) 658-9141
(302) 658-5614 (Fax)
Attorney for Applicant

479800